WORKINGAGE

Smart Working Environments for All Ages

D10.4 Standardisation Report

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WP10 – Dissemination, Exploitation Strategy and Value Chain Modelling

D10.4 – Standardisation Report

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Executive Summary

This report presents the outcome of activities carried out in the context of T10.4 "Standardization". As the standardization process plays a critical role in stimulating innovation, enabling market competition, and ensuring product interoperability, it is important to establish the standardization ecosystem landscape relating to both individual technologies and the WAOW tool system as a whole.

The WAOW tool solutions comprises an assembly of technological tools, working synergistically and in complementary fashion. These tools are: an environmental sensor, noise analysis tool, voice analysis tool, body posture analysis, facial affect analysis tool, gesture interaction tool, neurometric sensors and analysis, eye-tracking analysis tool. The sensors and tools interact through a custom IoT platform enabling secure communication between the deployed sensors and the edge-cloud servers processing information. The user interfaces with all tools through a custom mobile application, the WAOW tool, providing an integrated experience. The tool provides recommendations through a decision support system (DSS) to the user and it also has an Emergency 112 call functionality providing the user's location to the emergency services.

Given the standards utilized in the development of the WAOW tool technologies, the pathway for obtaining CE marking for the tool is broadly outlined as a rough guideline in case commercial exploitation of the WAOW solution is pursued. Through this process, any gaps in the present standardization landscape can be better identified.

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1. Introduction

The role of the standardization process is to stimulate innovation, enable competition in the market and ensure interoperability of products and services with similar scope. This process introduces additional benefits, such as cost reduction and improved safety. Europe's standardization policy actively improves regulation and enhances industrial competitiveness, and helps bring efficiency and trust to industry and consumers.

According to the European Commission [1], "Standards are technical specifications defining requirements for products, production processes, services or test-methods. These specifications are voluntary. They are developed by industry and market actors following some basic principles such as consensus, openness, transparency and non-discrimination. Standards ensure interoperability and safety, reduce costs and facilitate companies' integration in the value chain and trade."

European standards are developed through the following European Standards Organisations: the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI). The European Standardisation Organisations are officially recognized by Regulation (EU) No 1025/2012 [2] as providers of European standards.

During the first months of project activities, an exploration and identification of the standardization landscape was carried out, to serve as a guide during the development of the WAOW tool. The standards identified then are included in

Appendix 1 of this deliverable, and although recorded in the Appendix, form an essential contribution to the present report.

The purpose of this report is to:

- Report the standardization ecosystem landscape within which the WorkingAge project evolved;
- to identify gaps and future standardization possibilities;
- to document the compliance of the WAOW tool to standards and legal requirements, and best practices followed.

The report is organized as follows: Section 2 provides an overview of the developed solution. Sections 3 documents standards, directives and norms used/followed during the technical developments. Section 0 provides an overview of actions towards achieving CE marking for the WAOW tool; Section 5 documents the gaps identified during the course of the project and resulting recommendation for standardization activities. Finally, in Section 0, we provide our conclusions.

2. Overview

The WAOW tool is designed for workers aged over 45 with the aim to provide recommendations to promote healthy habits in their working environment and daily living. This is achieved by monitoring their environment with IoT devices (e.g., sensors, interaction tools, wearables), gathering information (e.g., voice emotions, facial expressions, body posture, environmental conditions), and generating recommendations for interventions for the user to follow at their discretion. The major advantage of the solution is that health recommendations are based on observing each user's behaviour, and thus can be made more accurate. At the same time, as the tool gathers private user data and other health-related data, relevant standards and legal requirements must be observed.

The WorkingAge platform consists of a number of IoT devices and sensors. Some of these sensors communicate raw data through a dedicated IoT platform and a custom communications protocol to edge servers that process the data and send back to the WAOW application on the user's mobile phone high-level messages about their state. The other sensors process the raw data locally and communicate the necessary information via Bluetooth to the mobile phone. All information is displayed to the user through the developed mobile application.

A summary of each component and its functionality is beyond the scope of this document. Instead, the components are summarized in Table 1, along with the partner responsible and a reference to the deliverable where the component is fully detailed.

Table 1 Summary of WorkingAge components

Component	**Responsible Partner**	**Full documentation reference**
Health surveillance assessment	INTRAS	D3.1
Cognitive/emotional assessment	RWTH	D3.2
User behaviour assessment	BS	D3.3
Interventions & Interaction	INTRAS	D3.4
Distributed device network	GC	D5.1
ZeroMQ communication	EXUS	D8.2
Visualization front-end	ITCL	D4.1
IoT Sensors	ITCL	D5.2
Noise Analysis	AUD	D4.3
Voice Interaction	PoliMi	D4.3
Facial Affect	UCAM	D4.5
Gesture interaction	EXUS	D4.2
Neurometrics	BS	D4.6
Location services	TPZ	D4.8
Eye tracking	RWTH	D4.4

3. Relevant Standards in the WorkingAge Project

Each of the components described in Section 2 adopts several existing standards relating to the type of data and sensor solutions. In Table 2 we summarize representative standards used in the tools of partners. These are organized into:

i) Intervention design related standards (WP3);

ii) HCI platform related standards (WP4); and

iii) IoT related standards (WP5).

Table 2 Representative existing standards used per component

WP	Tool	Standards, Directives & norms
3 - Intervention design	Health surveillance assessment	• SF-36 Questionnaire • Work Ability Index (WAI) (2007) • The Nordic Musculoskeletal Questionnaire (1987) • European Working Conditions Survey (2015) • The COPSOQ III Questionnaire (2019)
	Cognitive/emotional assessment	• ISO 10075 • COPSOQ Questionnaire • PHQ-D Questionnaire • PHQ-9 Questionnaire • GAD-7 Questionnaire • Nasa-TLX Questionnaire
	User behaviour assessment	• ZeroMQ
	Interventions & Interaction	• Web Ontology Language (OWL) from W3C (OWL-DL language) • REBA method • ISO 7730:2005 on *Ergonomics of the thermal environment* • Directive 89/654/CEE regulations • EN-12464-1:2012 - *Light and lighting - Lighting of workplaces* • ISO 7730:2006 for good indoor air quality • Directive 2017/2398 on CO2 exposure • Directive 2002/49/EC on noise at work
4 - HCI Platform	Visualization front-end	• Unity • C# • Android Studio • Java • XML

		• ARCore
	Body posture	• OpenCV • CUDA • Python • JSON • ZeroMQ • Tensorflow • RTSP • SSH/RSA 4096 • Unity
	Gesture interaction	• OpenCV • CUDA • Python • JSON • MongoDB • ZeroMQ • FFMpeg • TensorFlow • RTSP • SSH/RSA 4096
	Voice interaction	• Python • JSON • C++ • ZeroMQ • FFMpeg • FLAC • TensorFlow
	Facial affect	• Python • PyTorch • Keras • Dlib • Face-recognition • Numpy • OpenCV • Scipy • Matplotlib • DGL • ZeroMQ
	Eye-tracking	• C#
	Neurometrics	• Python • ZeroMQ • Matlab • Bluetooth
	Location services	• JSON • Https • PEMEA
5 - IoT	IoT local data collection	• OLSR • vCard
	IoT Sensors	• Bluetooth • C

A brief description for each standard follows:

- **Android Studio** is the official integrated development environment (IDE) for Google's Android operating system, built on JetBrains IntelliJ IDEA software and designed specifically for Android development. It is available for download on Windows, macOS and Linux based operating systems or as a subscription-based service in 2020. It is the primary IDE for native Android application development. (https://developer.android.com/studio)
- **ARCore** is Google's platform for building augmented reality experiences. Using different APIs, ARCore enables your phone to sense its environment, understand the world and interact with information. Some of the APIs are available across Android and iOS to enable shared AR experiences. (https://developers.google.com/ar/develop)
- **Bluetooth** is a short-range wireless technology standard that is used for exchanging data between devices over short distances using UHF radio waves in the ISM bands, from 2.402 GHz to 2.48 GHz, and building personal area networks (PANs). Bluetooth 5 features the Low Energy mode that was introduced with BLE (Bluetooth 4.2) but allows higher bandwidths and ranges. Bluetooth is managed by the Bluetooth Special Interest Group (SIG), which oversees development of the specification, manages the qualification program, and protects the trademarks. A manufacturer must meet Bluetooth SIG standards to market it as a Bluetooth device.
- **C** is a general-purpose computer programming language created in the 1970s by that remains very widely used and influential, more even so in microcontroller and embedded systems. This is so because it provides low- and high-level programming capabilities. By design, C's features cleanly reflect the capabilities of the targeted CPUs and is common in computer architectures that range from the largest supercomputers to the smallest microcontrollers and embedded systems.
- **CUDA** is a General-Purpose Parallel Computing Platform and Programming Model, introduced by NVIDIA®, which leverages the parallel compute engine in NVIDIA GPUs to solve many complex computational problems in a more efficient way than on a CPU. CUDA comes with a software environment that allows developers to use C++ as a high-level programming language. (https://docs.nvidia.com/cuda/)
- **C++** is a low-level general-purpose programming language, supporting object-oriented and functional programming paradigms. It is standardized by the ISO with ISO/IEC 14882:2020. (https://isocpp.org/)
- **C#** is a universal, multi-paradigm programming language. C# encompasses the disciplines of static typing, strong typing, lexical scaling, imperative, declarative, functional, generic, object-oriented (class-based) and component-oriented programming.
- **DGL** is a Graph Neural Network library that allow users to build models with PyTorch, TensorFlow or Apache MXNet. It allows to process giant graphs via multi-GPU acceleration and distributed training infrastructure.**Dlib** is a general purpose cross-platform software library written in the programming language C++. It is open-source software released under a Boost Software License. Dlib contains software components for dealing

with networking, threads, graphical user interfaces, data structures, linear algebra, machine learning, image processing, data mining, XML and text parsing, numerical optimization, Bayesian networks, and many other tasks.

- **FFMpeg** is a multimedia framework, able to decode, encode, transcode, mux, demux, stream, filter and play a considerably large amount of different kind of multimedia (audio and video) content. (https://www.ffmpeg.org)
- **FLAC (Free Lossless Audio Codec)** is an audio coding format for lossless compression of digital audio. (https://xiph.org/flac/format.html)
- **https**: Hypertext Transfer Protocol Secure (HTTPS) is an Internet based communication protocol protecting the integrity and confidentiality of data exchanged.
- **ISO 10075 Ergonomic principles related to mental workload** [4]**:** This standard is an extension of ISO 6385 in particular with regard to mental workload, detailing general aspects, concepts and terms (part 1) design principles (part 2) and methods for measurement (part 3).
- **Java** is a high-level, class-based, object-oriented programming language that is designed to have as few implementation dependencies as possible. It is a general-purpose programming language intended to let programmers *write once, run anywhere* (WORA), meaning that compiled Java code can run on all platforms that support Java without the need to recompile. Java applications are typically compiled to bytecode that can run on any Java virtual machine (JVM) regardless of the underlying computer architecture.
- **JSON** (JavaScript Object Notation) is a lightweight data-interchange format that is easy for humans to read and write, while also being easy for machines to parse and generate. It is based on a subset of the JavaScript Programming Language Standard ECMA-262 3rd Edition - December 1999. (https://www.json.org/json-en.html)
- **Matlab**: MATLAB (an abbreviation of "MATrix LABoratory") is a proprietary multi-paradigm programming language and numeric computing environment developed by MathWorks (https://www.mathworks.com/). MATLAB allows matrix manipulations, plotting of functions and data, implementation of algorithms, creation of user interfaces, and interfacing with programs written in other languages.
- **OLSR:** The Optimized Link State Routing Protocol (OLSR) is an IP routing protocol optimized for mobile ad hoc networks - a decentralized type of wireless network (https://en.wikipedia.org/wiki/Wireless_ad_hoc_network)
- **OpenCV** (Open Source Computer Vision Library) is an open source computer vision and machine learning software library. OpenCV was built to provide a common infrastructure for computer vision applications and to accelerate the use of machine perception in the commercial products. (https://opencv.org/about/)
- **PEMEA**: Pan-European Mobile Emergency Application (PEMEA) is an architecture defined in the ETSI Technical Specification 103 478 allowing mobile applications to provide accurate location and user information to the correct emergency answering point.

- **Python** is a high-level, interpreted, general-purpose programming language, supporting structured, object-oriented, and functional programming paradigms. (https://www.python.org/). Several common Python libraries are also used, described below:
    - **Numpy** is a library for the Python programming language, adding support for large, multi-dimensional arrays and matrices, along with a large collection of high-level mathematical functions to operate on these arrays.
    - **PyTorch** is an open source machine learning framework based on the Torch library, used for applications such as computer vision and natural language processing. It is a free and open-source software released under the Modified BSD license, which also has a C++ interface. PyTorch provides two high-level features: (i) Tensor computing with strong acceleration via graphics processing units; and (ii) Deep neural networks built on a tape-based automatic differentiation system.
    - **Keras** is an open-source software library that provides a Python interface for artificial neural networks. It contains numerous implementations of commonly used neural-network building blocks such as layers, objectives, activation functions, optimizers, and a host of tools to make working with image and text data easier to simplify the coding necessary for writing deep neural network code.
    - **Face-recognition** is a Python library that allows users to use simple command line to recognize and manipulate faces from Python or from the command line with the world's simplest face recognition library.
    - **Scipy** is a free and open-source Python library used for scientific computing and technical computing. It contains modules for optimization, linear algebra, integration, interpolation, special functions, FFT, signal and image processing, ODE solvers and other tasks common in science and engineering.
    - **Matplotlib** is a plotting library for the Python programming language and its numerical mathematics extension NumPy. It provides an object-oriented API for embedding plots into applications using general-purpose GUI toolkits like Tkinter, wxPython, Qt, or GTK.
- **RTSP** is the Real Time Streaming Protocol used to control the streaming of video over the deployed network. (https://en.wikipedia.org/wiki/Real_Time_Streaming_Protocol)
- **SSH/RSA 4096** is a network protocol that gives system administrators a secure way to access remote assets over an unsecured network. (https://en.wikipedia.org/wiki/Secure_Shell)
- **TensorFlow** TensorFlow is open source platform for machine learning (ML). It has a comprehensive, flexible ecosystem of tools, libraries, and community resources that lets researchers and developers easily build and deploy ML-powered applications. (https://www.tensorflow.org)

- **Unity** is a cross-platform game engine developed by Unity Technologies. The engine has since gradually extended to support a variety of desktop, mobile, console and virtual reality platforms. It is also popular for iOS and Android mobile game development. Unity gives users the ability to create game experiences in both 2D and 3D. (https://unity.com/)
- **vCard:** vCard, also known as VCF (Virtual Contact File), is a file format standard for electronic business cards. It includes a customizable list of fields such as name, address, email, URL, coordinates, etc/ (https://en.wikipedia.org/wiki/VCard)
- **XML** (Extensible Markup Language) is a markup language and file format for storing, transmitting, and reconstructing arbitrary data. It defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. The World Wide Web Consortium's XML 1.0 Specification of 1998 and several other related specifications—all of them free open standards—define XML. The design goals of XML emphasize simplicity, generality, and usability across the Internet. It is a textual data format with strong support via Unicode for different human languages. Although the design of XML focuses on documents, the language is widely used for the representation of arbitrary data structures such as those used in web services.
- **ZeroMQ** (also spelled ØMQ, 0MQ or ZMQ) is an asynchronous messaging library, aimed at use in distributed or concurrent applications. It provides a message queue, but unlike message-oriented middleware, a ZeroMQ system can run without a dedicated message broker. ZeroMQ supports common messaging patterns (like pub/sub) over a variety of transports (like TCP/IP). (https://zeromq.org)
- The fundamental evaluation instrument to get information regarding the ***health assessment*** of the participants involved in the WA project and depict their daily workflow is a survey made up of the different scales and sets of questions that will form the assessment tool of the WorkingAge system.
- Several standardised and validated ***emotional and cognitive assessment questionnaires*** were used, including the COPSOQ questionnaire for assessing psychosocial stress at work, parts of the PHQ-D questionnaire for screening and diagnosing mental disorders, and the Nasa-TLX questionnaire for assessing workload
- Different standards were used for the ***interventions and interaction design***, namely OWL-DL language for the WAOW tool Ontology and the REBA method for ergonomic evaluation, and for defining comfort and safety thresholds on different aspects. ISO 7730:2005 defines the indices for local thermal comfort criteria, EN-12464-1:2012 sets thresholds for comfort Lighting of work places, ISO 7730:2006 establish safe limits for good indoor air quality, Directive 2017/2398 on CO2 concentration levels recommended for long term and short-term exposure. Two Directives were considered: Directive 89/654/CEE regulations defines discomfort warning thresholds for low and high relative humidity levels, and Directive 2002/49/EC defining noise at work thresholds based on the environmental

noise level necessary to be able to carry out mental processes without interference.

4. Roadmap to CE Marking

In this Section, the general process for obtaining CE Marking is outlined, to serve as a guide for the WorkingAge consortium.

4.1 CE Marking for Individual Components

The WorkingAge system consists of a collection of sensors, some of which are commercial products already bearing the CE mark, while others being custom designed sensors. The conformity of the commercial sensors is documented in Table 3. The remaining custom sensors are:

i) The **Environmental Sensor**: This consists of a custom designed integrated circuit with sensors for measuring temperature, humidity, atmospheric levels of carbon dioxide and ambient light intensity. The device is powered by a rechargeable battery. The device has Bluetooth connectivity. Given the above features, the device should -at minimum- seek conformity to the following directives:
   a. The *RoHS2 Directive* (2011/65/EU) – regarding the use of hazardous substances
   b. The *Radio Equipment Directive* (2014/53/EU) – regarding the use of telecommunication equipment

ii) The **NoiseBox**: This consists of a Raspberry-Pi single board computer with an LCD (liquid-crystal display), microphone and sound-blaster adapter, packaged in a custom 3D printed enclosure. The conformity to CE marking of the Raspberry-Pi is included in Table 3. The conformity of the NoiseBox system should also be pursued by seeking conformity with the *RoHS2 Directive*.

iii) The **YOI Router**: This consists of an embedded Linux router equipped with Green Communications' software (GreenSoft). Each router comes with 2 Wi-Fi interfaces: one to create a network with other YOI, and the other to provide access to smartphones, tablets, laptops, or any other Wi-Fi device. Some of the device hardware (e.g. the power supply) are CE certified, while others (e.g. the radios used) are CE and FCC certified. Given the above features, the device should -at minimum- seek conformity to the following directives:
   a. The *RoHS2 Directive* (2011/65/EU) – regarding the use of hazardous substances
   b. The *Radio Equipment Directive* (2014/53/EU) – regarding the use of telecommunication equipment

Table 3 Commercial sensors and other devices used in the WorkingAge System and their declaration of conformity to EU standards and CE marking

Device	Conformity to CE
Jabra 65e	Declaration of conformity
Dahua IPC-HFW1320S-W	Declaration of conformity
Raspberry Pi	Model 3B declaration of conformity Model 4B declaration of conformity
Xiaomi Mi Note 10 Lite	Declaration of conformity
Xiaomi SmartBand 4	Declaration of conformity
Xiaomi Body Composition Scale 2	Declaration of conformity
Empatica E4	CE certificate
Muse S	Statement by manufacturer

4.2 CE Marking for the WorkingAge System

In the present section, we will assume that all comprising components of the WAOW tool individually carry the CE Marking. Also, we state that the WorkingAge Tool is not a medical device; instead it is intended as a tool to provide information that can help manage and support the user's wellbeing. The individual components are used according to their original intent and only the information generated through their use is combined for recommendations to improve the user's wellbeing.

With the above in mind, the process for obtaining CE marking, according to [3], may be summarized as:

Ensure conformity with all relevant EU requirements.

As a collection of CE-certified devices, the whole WAOW tool itself will also comply with all the relevant EU requirements, therefore conformity is ensured. The relevant standards have been identified in Section 3 and

1. Appendix 1 of the present document.
2. **Perform an assessment, either self-assessment or through a notified body**. The objective of this conformity assessment is to demonstrate that the product complies with all legislative requirements and to ensure the confidence of consumers, public authorities and manufacturers regarding the conformity of the product. For the case of the WAOW tool, a self-assessment is deemed sufficient, again owing to the fact that it is a collection of devices already conforming to EU directives.
3. **Collect a technical dossier documenting conformity.** The technical documentation should include information about the manufacturer/owner (e.g. a spin-off commercializing the WAOW tool and list of partners involved), a brief description of the product, the declaration of conformity of comprising sensors, labels and instructions of use, a statement of relevant regulations to which the product complies, identification of technical standards with which compliance is claimed, a list of parts, results of any test performed.
4. **Draft and sign an EU Declaration of Conformity.** The declaration of conformity should be made available to any authorities requesting it.

5. Gaps & Recommendations

The WorkingAge solution aims to help workers over 45 improve their well-being and occupational health and safety through customized notifications based on observations. Although health-related data are used as the basis of the observations and the interventions can impact the user's wellbeing and physical and mental health, the tool itself is not a medical tool, rather an ICT tool.

In reviewing the relevant standards presented in *Appendix 1: Overview of Current Standards*, a gap exists for tools such as the WAOW tool that live in the space between purely medical and purely ICT solutions. Tools such as digital health assistants, could benefit from some level of standardization, which could enable market competition and ensure the interoperability of devices, products and services with similar scope.

6. Summary & Conclusions

In the present report, an overview of the WAOW tool and the standardization ecosystem landscape relating the tools and technologies used in its development is presented. The standardization landscape was defined in the early stages of the project, setting the scene for the implementation and development efforts to follow. The actual norms and standards implemented are also documented. A necessary step for the commercialization of the WAOW tool is the process of obtaining CE marking, and a roadmap with the critical steps of the process is outlined.

The conclusions that may be drawn from the above are that a wide set of standards and norms have been followed in the development of the technical solutions comprising the WAOW tool and the questionnaires assessing user health status and tool acceptability. Similarly, to a large extent the individual sensors used already comply with CE Marking, thus significantly simplifying the process of obtaining CE Marking for the WAOW tool as a whole. We believe that there is a gap in the standardization landscape relating to non-medical devices intended for improving the wellbeing of humans.

References

1. EC, European Standards, https://ec.europa.eu/growth/single-market/european-standards_en
2. EU Regulation 1025/2012, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1025&from=EN
3. EC, CE Marking, https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm
4. ISO 10075-1:2017, https://www.iso.org/standard/66900.html

Appendix 1: Overview of Current Standards

Table 4 presents the standards and relevant bodies corresponding to each technical component of the WA Tool. These standards were compiled during the first months of the project (M1-M4), to server as a snapshot of the standardization landscape then, and as a guide to be considered by the technical partners developing or integrating individual technologies.

Table 4 Standards and standardisation bodies related to WA technologies

Standard	Standardisation Body	Standard Description	Relevant task
Ethics requirements for Clinical studies			
EU Regulation No 536/2014	EU	The Regulation will ensure a greater level of harmonisation of the rules for conducting clinical trials throughout the EU. It introduces an **authorisation procedure based on a single submission via a single EU portal**, an assessment procedure leading to a single decision, rules on the protection of subjects and informed consent, and transparency requirements	Clinical pilots/trials on human subjects
ISO 14155	ISO	This international standard addresses good clinical practices for the **design, conduct, recording and reporting of clinical investigations carried out in human subjects** to assess the safety and performance of medical devices for regulatory purposes. However, it does not apply to in vitro diagnostic medical devices	Clinical pilots/trials on human subjects
EFGCP Report	EFGCP	EFGCP is a non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research. Its purpose is to **promote Good Clinical Practice (GCP) and encourage the practice of common, high-quality standards in all stages of biomedical research** throughout Europe and globally. The EFGCP does this by promoting contact and partnership between the major disciplines and organisations affected by good clinical practice	Regulatory issues in clinical research

Interoperability/Communication protocols			
IEEE 1451	IEEE	The IEEE 1451, a family of Smart Transducer Interface Standards, describes a set of open, **common, network-independent communication interfaces for connecting transducers (sensors or actuators)** to microprocessors, instrumentation systems, and control/field networks	Sensors connection
IEEE 1888.3-2013	IEEE	IEEE Standard for **Ubiquitous Green Community Control Network: Security.** Security requirements, system security architecture definitions, and a standardised description of authentication and authorisation, along with security procedures and protocols, are specified. This standard can help avoid unintended data disclosure to the public and unauthorised access to resources, while providing enhanced integrity and confidentiality of transmitted data in the ubiquitous green community control network	Security of control network
IEEE 1905.1-2013	IEEE	IEEE Standard for **a Convergent Digital Home Network for Heterogeneous Technologies**	Connection of heterogeneous technologies
IEEE 802.16p-2012	IEEE	IEEE Standard for **Air Interface for Broadband Wireless Access Systems**	Broadband wireless access systems development
IEEE 1377-2012	IEEE	IEEE Standard for **Utility Industry Metering Communication Protocol Application Layer**	Communication protocol
IEEE P1828	IEEE	Standard for **Systems with Virtual Components**	Virtual Reality components
IEEE P1856	IEEE	Standard Framework for **Prognostics and Health Management of Electronic Systems**	Health management of electronics
FHIR	HL7	**Mobile, Web, exchange protocol for patient health records**	Interoperability regarding patient health records
Auto Blue Button (ABBI) – S&I Framework	Blue Button initiative	**Mobile, Web apps, small Healthcare organisations, connection to HIE**	Interoperability regarding patient health records

Digital Imaging and Communications in Medicine (DICOM)	ACR	Standards for exchanging medical images. Digital Imaging and Communications in Medicine (DICOM) is a standard for **exchanging medical images**. More specifically, it is a **file format and transmission standard for exchanging medical images and associated information between medical imaging equipment made by different manufacturers**. The DICOM standards are widely adopted in equipment and information systems used in hospitals, imaging centres, and in providers' offices to produce, display, store, or exchange medical images	Digital images transmission in Medicine
ISO standard 12052:2017	ISO	ISO 12052:2017, within the field of health informatics, addresses the **exchange of digital images and information related to the production and management of those images**, between both medical imaging equipment and systems concerned with the management and communication of that information	Digital Images exchange
IEEE 802.15.6 TM-2012	IEEE	Short-range, **wireless communications in the vicinity of, or inside, a human body** (but not limited to humans) are specified in this standard. It uses existing industrial scientific medical (ISM) bands as well as frequency bands approved by national medical and/or regulatory authorities. Support for quality of service (QoS), extremely low power, and data rates up to 10 Mbps is required while simultaneously complying with strict non-interference guidelines where needed	Body sensors, implants, diagnostics
ISO/IEEE 11073 (see also CONTINUA Design Guidelines below)	ISO, IEE	Medical/Health Device Communication Standards are a set of joint ISO, IEEE, and CEN standards for medical device interoperability. In this context, medical devices include primarily personnel, or end user, health devices such as blood glucose monitors, blood pressure monitors, thermometers, pulse oximeters, etc., that patients use in their own homes or other end points to monitor existing medical conditions. The ISO/ IEEE 11073 (formerly called IEEE 1073) standards define **messaging structures** but not the transport layer upon which messages are transmitted	Medical device interoperability

CONTINUA Design Guidelines	Fujitsu, Intel, Oracle, Orange, Philips, Qualcomm, Roche, Sharp, UnitedHealth	PCH Alliance publishes and promotes the Continua Design Guidelines, the only open implementation framework for authentic, end-to-end interoperability of personal connected health devices and systems. The Continua Design Guidelines are based on common international standards defined by recognized standards development organizations, and are built on four key principles: Unity: The best clinical minds united with the best technical minds to deliver and scale remote monitoring worldwide. Benevolent: The spirit of doing what we collectively believe is right for all persons is also freely and universally accessible. Inclusive: Inputs and improvements from any person are heard and considered. Holistic: We passionately work together to enable holistic understanding to make big data research possible	Medical device interoperability
ISO 18000-7	ISO	ISO/IEC 18000-7:2009 **defines the air interface for radio frequency identification (RFID) devices** operating as an active RF tag in the 433 MHz band used in item management applications. It provides a common technical specification for RFID devices that can be used by ISO technical committees developing RFID application standards. ISO/IEC 18000-7:2009 is intended to allow for compatibility and to encourage inter-operability of products for the growing RFID market in the international marketplace. ISO/IEC 18000-7:2009 defines the forward and return link parameters for technical attributes including, but not limited to, operating frequency, operating channel accuracy, occupied channel bandwidth, maximum power, spurious emissions, modulation, duty cycle, data coding, bit rate, bit rate accuracy, bit transmission order, and, where appropriate, operating channels, frequency hop rate, hop sequence, spreading sequence, and chip rate	Interoperability among mobile devices

CEN/TC 251	CEN, TC	The focus of CEN/TC 251 is primarily on technologies at the content level rather than dealing with communication technologies. CEN/TC 251 is further broken down into working groups such as Working Group IV, which focuses on the **interoperability of data among devices and information systems.**	Interoperability of data among devices and information systems
ISO/TC 215	ISO, TC	ISO's Technical Committee 215 addresses health informatics. ISO/TC 215 focuses primarily on **electronic health records**. Various Working Groups (WGs) within TC 215 address topics such as **data structure, messaging and communication, security, pharmacy and medication, devices, and business requirements for electronic health records**	Health informatics and electronic health records
Risk Management			
ISO 14971:2007	ISO	ISO 14971:2007 **specifies a process for a manufacturer to identify the hazards associated with medical devices**, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. the requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device	Application of risk management to medical devices
ISO/IEC 27000-series (also known as the 'ISMS Family of Standards' or 'ISO27K')	ISO, IEC	Best **practice recommendations on information security management** - **the management of information risks** through information security controls - within the context of an overall Information Security Management System (ISMS)	Risk management and Controls of Information Security

IEC 80001	IEC	IEC 80001-1:2010 Recognising that medical devices are incorporated into IT-networks to achieve desirable benefits (for example, interoperability), **defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security** (the key properties). IEC 80001-1:2010 does not specify acceptable risk levels. IEC 80001-1:2010 applies after a medical device has been acquired by a responsible organisation and is a candidate for incorporation into an IT-network. It applies throughout the life cycle of IT-networks incorporating medical devices	Risk management of Medical Devices
Ergonomic Assessment & Metrics			
ISO/TC 159	ISO, TC	Standardisation in the field of **ergonomics, in particular, general ergonomics principles, anthropometry and biomechanics, ergonomics of human system interaction and ergonomics of the physical environment**, addressing human characteristics and performance, and methods for specifying, designing and evaluating products, systems, services, environments and facilities	Ergonomic assessment and metrics
ISO/TC 159/SC 3	ISO, TC	**Ergonomics of HCI.** It includes ISO/TC 159/SC3/WG1 - Anthropometry, ISO/TC 159/SC3/WG4 - Human physical strength: manual handling and force limits	Ergonomic assessment and metrics
ISO/TC 94	ISO, TC	Personal safety - **Personal protective equipment**	Personal protective equipment assessment
ISO 10075-1:2017	ISO	Ergonomic principles related to mental workload: General issues and concepts, terms and definitions	Ergonomic background
ISO 10075-2:2000	ISO	Ergonomic principles related to mental workload - Part 2: Design principles	Ergonomic design principles
ISO 10075-3:2004	ISO	Ergonomic principles related to mental workload - Part 3: Principles and requirements concerning methods for measuring and assessing mental workload	Ergonomic assessment

Noise Pollution			
Directive 2003/10/EC	EC	The Directive defines the physical parameters that serve as risk predictors, such as **peak sound pressure, daily noise exposure level and weekly noise exposure level**. It sets exposure limit values and exposure action values in respect to the daily and weekly noise exposure level as well as peak sound pressure	Noise pollution assessment
Health & Safety at Work			
Directive 89/391/EEC	EC	The aim of this Directive is to introduce measures to encourage improvements in the safety and health of workers at work. It applies to all sectors of activity, both public and private, except for specific public service activities, such as the armed forces, the police or certain civil protection services (that includes **manual handling of loads**, **temperature**, **humidity**, **ventilation**, etc)	Generic Health & Safety assessment
Vibrations			
ISO 2631-5:2018	ISO	**Mechanical vibration and shock** -- Evaluation of human exposure to whole-body vibration	Vibration levels assessment
Air (Environmental) pollution			
Directive 2008/50/EU (and 2004/107/EC)	EC	**Air quality framework directive**	Air quality assessment
Lightning			
EN12464-1:2011	CEN	**Light and lighting** - Lighting of work places - Part 1: Indoor work places	Light and lightning assessment
Collaborative Robots			
ISO/TS 15066	ISO, TC	ISO/TS 15066:2016 specifies safety requirements for **collaborative industrial robot systems and the work environment,** and supplements the requirements and guidance on collaborative industrial robot operation given in ISO 10218-1 and ISO 10218-2	Collaboration between industrial robots

ISO 13849	ISO	ISO 13849-1:2015 provides **safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software.** For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS for high demand and continuous mode, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery	Safety requirements for the design and integration of safety-related parts of control systems
ISO 10218	ISO	ISO 10218-1:2011 specifies **requirements and guidelines for the inherent safe design, protective measures and information for use of industrial robots.** It describes basic hazards associated with robots and provides requirements to eliminate, or adequately reduce, the risks associated with these hazards	Protective measures for industrial robots
Manufacturing Operations Management			
ISA-95 (IEC 62264)	IEC	IEC 62264 is an **international standard for enterprise-control system integration.** This standard is based upon ANSI/ISA-95. It consists of: Part 1:2013 Object Models and Attributes of Manufacturing Operations, Part 2:2013 Object model attributes, Part 3:2016 Activity models of manufacturing operations management, Part 4:2015 Objects models attributes for manufacturing operations management integration, Part 5:2016 Business to manufacturing transactions PAS, Part 6:2016 Messaging Service Model	Personnel and resources capability information
Evaluation of Communication Activities			
Directorate General for Communication	EC	This toolkit provides **guidance on the planning and undertaking of evaluation of communication actions.** It was developed by ICF-GHK in the context of the project "Measuring the European Commission's communication: Technical and Methodological Report" under Lot 3 – Provision of services in the field of evaluation of communication activities of the Multiple Framework Contract (PO/2012-3/A3)	Dissemination activities

Touch Screen & Gesture-based Interfaces			
ISO/IEC 30113-1:2015	ISO, IEC	ISO/IEC 30113-1:2015 defines a **framework and guidelines for gesture-based interfaces** across devices and methods in supporting interoperability. Some of these devices include mice, touch screens, touch pads, 3D mice, joysticks, game controllers, wired gloves, depth-aware cameras, stereo cameras, Web cameras	Gesture-based interfaces development
ISO 7000 / IEC 60417	ISO, IEC	This collection includes both ISO and IEC graphical **symbols that can be placed on equipment to indicate how to use it correctly and safely**. It includes symbols for all types of equipment, from automobiles and home entertainment products to earth-moving machinery. The symbols are available in four formats: .eps, .ai, and .dwg for ISO 7000, and PDF for IEC 60417	Interface design
ISO/IEC 24755:2007	ISO, IEC	ISO/IEC 24755:2007 defines a consistent **set of screen icons and symbols, together with their related functions, that are presented by personal mobile communications devices** (e.g. mobile phones and personal digital assistants). These devices have touch screens accessible by stylus pen, finger or button with personalised application	Interface design
(Personal and Clinical) Data Protection			
GDPR	EU	The EU General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and is designed to: Harmonise data privacy laws across Europe, **Protect and empower all EU citizens data privacy**, Reshape the way organisations across the region approach data privacy	Personal data use and processing
ECRIN data certification standards	EC	The ECRIN Data Centre Certification programme identifies non-commercial clinical trials units in Europe that have demonstrated they can provide safe, secure, compliant and efficient management of clinical research data. It does so by testing the units for compliance with published ECRIN data standards, using an on-site audit of the unit's data management activities and of the IT infrastructure used to support those activities	Clinical data management